**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF OHIO**

| | | |
|---|---|---|
| **LAUREN BOSSETTI, individually and as mother and next friend of S.R. Bossetti, et al.,** | ) | **CASE NO: 1:22-cv-00523-DRC** |
| | ) | |
| | ) | **ORAL ARGUMENT REQUESTED** |
| **Plaintiffs,** | ) | |
| | ) | |
| **v.** | ) | |
| | ) | |
| **ALLERGAN SALES, LLC,** | ) | |
| | ) | |
| **Defendant.** | ) | |

**DEFENDANT ALLERGAN SALES LLC'S MOTION TO DISMISS PLAINTIFFS' COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendant Allergan Sales LLC, respectfully moves to dismiss Plaintiffs' Complaint. In support of this Motion, Allergan Sales LLC relies on its Memorandum in Support attached.

Dated: January 9, 2023

Respectfully submitted,

*/s/ Jennifer Snyder Heis*

Jennifer Snyder Heis (0076181)
John R. Ipsaro (0062300)
ULMER & BERNE LLP
312 Walnut Street, Suite 1400
Cincinnati, Ohio 45202
Telephone: 513-698-5058
Facsimile: 513-698-5059
jheis@ulmer.com
jipsaro@ulmer.com

Bert L. Wolff
(*motion for admission PHV to be filed*)
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, New York 10036-6797
Telephone: 212-698-3548
Facsimile: 212-698-3599
bert.wolff@dechert.com

Jonathan S. Tam
(*motion for admission PHV to be filed*)
DECHERT LLP
One Bush Street
San Francisco, CA 94104-4446
Telephone: 415-262-4518
Facsimile: 415-262-4555
jonathan.tam@dechert.com

***Attorneys for Defendant***
***Allergan Sales, LLC***

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF OHIO**

| | | |
|---|---|---|
| **LAUREN BOSSETTI, individually and as mother and next friend of S.R. Bossetti, et al.,** | ) | **CASE NO: 1:22-cv-00523-DRC** |
| | ) | **ORAL ARGUMENT REQUESTED** |
| **Plaintiffs,** | ) | |
| **v.** | ) | |
| **ALLERGAN SALES, LLC,** | ) | |
| **Defendant.** | ) | |

**DEFENDANT ALLERGAN SALES LLC'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS PLAINTIFFS' COMPLAINT**

**TABLE OF CONTENTS**

## TABLE OF AUTHORITIES

**CASES**

**STATUTES**

**RULES AND REGULATIONS**



**OTHER AUTHORITIES**

## I. INTRODUCTION

Three Plaintiffs from three states—Ohio, New Jersey, and Virginia—allege that their use of Lexapro, an FDA-approved SSRI antidepressant, during pregnancy caused their children to develop autism spectrum disorder (ASD). This is not the first case to advance such allegations. In the first suit of its kind nationally, the Southern District of New York rendered summary judgment in the defendants' favor after excluding the plaintiffs' expert testimony regarding the alleged causal relationship between Lexapro and ASD. *Daniels-Feasel v. Forest Pharms., Inc.*, 2021 WL 4037820 (S.D.N.Y. 2021); *Daniels-Feasel v. Forest Pharms., Inc.*, 2021 WL 6137093 (S.D.N.Y. 2021), *appeal pending*, No. 22-146 (2d Cir.).

Here, the Complaint runs the gamut of common law and statutory product liability claims, but these claims all are premised on the same notion: Plaintiffs allege that Defendant defectively designed Lexapro and failed to adequately warn of the risk of ASD. Yet, the majority of Plaintiffs' claims fail, as a matter of law, for multiple and independent reasons.

*First*, federal law preempts Plaintiffs' design defect claims. Lexapro is an FDA-approved prescription medication. The Sixth Circuit and courts throughout the country repeatedly hold that federal law preempts design defect theories involving prescription medications. This is because a pharmaceutical manufacturer could not redesign the medication or design a "safer alternative," if at all, without first obtaining FDA's approval. *See Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281 (6th Cir. 2015).

*Second*, nearly all of Plaintiffs' common law claims are not recognized under applicable state laws. Both Ohio's and New Jersey's Product Liability Acts (PLA) preclude Plaintiffs' common law claims, as they provide the exclusive remedy for product liability claims under each state's laws. Plaintiffs also attempt to plead a strict liability claim that is not recognized under Virginia law and thus fails as a matter of law.

*Finally*, Ohio's and New Jersey's PLA and federal preemption principles prohibit Plaintiffs' recovery of punitive damages for claims related to FDA-approved medications, such as Lexapro.

## II. FACTUAL BACKGROUND

Lexapro (escitalopram) is a prescription antidepressant in a pharmaceutical class known as selective serotonin reuptake inhibitors (SSRIs). Lexapro is approved by FDA for the treatment of major depressive disorder and generalized anxiety disorder.[1]

The first litigation alleging that the maternal use of an SSRI—there, as here, Lexapro—causes autism in offspring was a multi-plaintiff action, *Daniels-Feasel v. Forest Pharms., Inc.*, No. 17-cv-04188-LTS-JLC (S.D.N.Y.). The parties agreed to a discovery schedule that staged the litigation so that the threshold question of general causation—*i.e.*, whether maternal use of Lexapro during pregnancy causes autism in offspring—would be addressed first, ahead of specific causation and other case-specific issues.[2] *Id*., Dkt. [35], [67], [95]. Defendants moved, under Federal Rule of Evidence 702 and *Daubert* and its progeny, to exclude the three experts who plaintiffs disclosed in support of general causation. *Id*., Dkt. [79], [80]. In 2021, in a thorough and thoughtful opinion, Chief Judge Swain granted that motion in its entirety. *Daniels-Feasel*, 2021 WL 4037820. In so ruling, among other things, the *Daniels-Feasel* court found that the plaintiffs' epidemiologist's opinion that maternal use of SSRIs during gestation is a cause of

[1] FDA, *Drugs@FDA: FDA-Approved Drugs*, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021323. In deciding a motion to dismiss, the court may "take judicial notice of matters of public record including records of the FDA available on its website." *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 794 n.1 (N.D. Ohio 2012); *accord Mories v. Boston Scientific Corp.*, 494 F. Supp. 3d 461, 469 (S.D. Ohio 2020); *Jones v. City of Cincinnati*, 521 F.3d 555, 562 (6th Cir. 2008). The Lexapro labeling and approval documents are publicly available on FDA's website.

[2] Defendants did not file a motion to dismiss in *Daniels-Feasel*.

autism "is not generally accepted" and "no regulatory agency, professional organization, peer-review study, or medical treatise concludes that Lexapro causes ASD, and the FDA has approved its prescription to pregnant women." *Id.* at *7. That ruling led to summary judgment on all claims. *Daniels-Feasel*, 2021 WL 6137093, at * 3.

The three Plaintiffs here, as in *Daniels-Feasel*, allege they were prescribed and used Lexapro during their pregnancies, and that Lexapro use caused their children to develop autism. Dkt. [1], Compl. ¶¶ 1–3, 85. The Complaint alleges that Lexapro "was defectively designed, inadequately tested, dangerous to human health and unborn, and lacked proper warnings as to the true danger associated with its use." *Id*. ¶¶ 1–3. Plaintiffs bring common law causes of action for strict liability (Count I), negligence (Count II), breach of implied and express warranty (Counts III–IV), and failure to warn (Count V). In the alternative to their common law claims, Plaintiff Bossetti brings causes of action under Ohio's Product Liability Act (Counts VI–VIII), and Plaintiff DiMeglio brings a cause of action under New Jersey's Product Liability Act (Count IX).

All three Plaintiffs' design defect claims should be dismissed as a matter of law. In addition, Plaintiff Bossetti's common law and punitive damages claims should be dismissed under the Ohio Product Liability Act. Likewise, Plaintiff DiMeglio's common law and punitive damages claims should be dismissed under the New Jersey Product Liability Act. Plaintiff Guida's strict liability claim should be dismissed under Virginia law.[3]

[3] If the Court were to grant Defendant's motion in full, the surviving claims would be as follows: for Plaintiff Bossetti, Counts VII and VIII; for Plaintiff DiMeglio, Counts IV and IX; and for Plaintiff Guida, Counts II-V. Defendant reserves its right to move against the remaining claims at a later stage in this litigation, on grounds including, without limitation, the preemption of the failure to warn claims.

## III. STANDARD OF REVIEW

A Court should grant a motion to dismiss under Rule 12(b)(6) if there is an "absence of law to support a claim of the type made or of facts sufficient to make a valid claim, or where the face of the complaint reveals that there is an insurmountable bar to relief." *Little v. UNUMProvident Corp.*, 196 F. Supp. 2d 659, 662 (S.D. Ohio 2002) (citing *Rauch v. Day & Night Mfg. Corp.*, 576 F.2d 697 (6th Cir. 1978)). "[A] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible only if the plaintiff alleges enough facts to draw a reasonable inference that the defendant is liable. *Id*. Likewise, on a motion to dismiss, "courts need not accept 'conclusory allegations or legal conclusions masquerading as factual allegations.'" *U.S. ex rel. Harper v. Muskingum Watershed Conservancy Dist.*, 842 F.3d 430, 435 (6th Cir. 2016) (citation omitted).

## IV. LAW AND ARGUMENT

### A. Plaintiffs' Design Defect Claims Are Preempted By Federal Law.

#### 1. Federal law regulates pharmaceutical products.

Prescription drugs are regulated under the Federal Food, Drug, and Cosmetic Act (FDCA), which is implemented and enforced by FDA. *See* 21 U.S.C. § 301 *et seq.*; *id.* §§ 371, 393. A pharmaceutical product may not be marketed or sold in interstate commerce unless approved by FDA. *See id.* § 355(a). For a new drug like Lexapro, FDA requires submission of a new drug application (NDA). FDA's review process is "onerous and lengthy." *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 476 (2013).

In reviewing an NDA, a team of FDA physicians, chemists, statisticians, microbiologists, pharmacologists, and other experts scrutinize all aspects of the drug, "from the design of clinical

trials to the severity of side effects to the conditions under which the drug is manufactured."[4] FDA may also consult the sponsor and independent scientific experts. *See* 21 U.S.C. § 355(b)(5), (n). NDA applicants must demonstrate that the new drug (or a new use for an old drug) is safe and effective for the proposed use before approval is granted. *See id.* § 355(b)(1)(A), (c), (d). Determinations of safety and efficacy are inextricably intertwined with the drug's use under the conditions set forth in the proposed labeling, which "serves as the standard under which FDA determines whether a product is safe and effective." *New Drug and Antibiotic Regulations*, 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985); *see also* 21 U.S.C. § 355.

After approval, manufacturers are required to maintain records, conduct additional testing as directed, and advise FDA of significant reported adverse health consequences. *See* 21 U.S.C. § 355(k)(1); 21 C.F.R. § 314.80. FDA monitors adverse event reports and uses that information to update drug labeling.[5] Absent FDA's express prior approval, manufacturers may not make any changes to the "qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application." 21 C.F.R. § 314.70(b)(2)(i).

**2. Federal law preempts Plaintiffs' design defect claims.**

Plaintiffs bring claims under a "design defect" theory. *E.g.*, Compl. ¶¶ 1–3, 77–79, 87–88, 109–124, 154–156. Under their theory, as articulated in the Complaint, Defendant was required to redesign Lexapro in a different and allegedly safer manner. Yet, federal law prohibits a manufacturer from changing an approved pharmaceutical's labeling, indication, dosage or

[4] FDA, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective.
[5] FDA, *Postmarketing Surveillance Programs* (Apr. 2, 2020), https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs.

formulation without prior FDA approval. *See* 21 U.S.C. § 301 *et seq*. This is precisely the type of improper claim that the U.S. Supreme Court, Sixth Circuit, and other courts throughout the country have held to be preempted by federal law.

FDA approved Lexapro as a safe and effective medicine in 2002.[6] "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Bartlett*, 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)); *accord Yates*, 808 F.3d at 298. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 623–24 (2011). Thus, because Lexapro cannot be redesigned without FDA's approval, design defect claims involving Lexapro are preempted.

The Sixth Circuit's decision in *Yates*, affirming the preemption of design defect claims, is controlling. 808 F.3d 281. There, the plaintiff had a stroke after using an FDA-approved birth control patch and sued the manufacturers for various claims under New York law, including defective design. *Id.* at 287–88. The plaintiff argued that, even after FDA approved the medication, the defendants had a duty to change the design once they discovered it was "unreasonably dangerous." *Id.* at 297–98. The plaintiff also argued that the defendants had a duty to design a different medication in the first instance, before obtaining FDA approval. *Id.* As framed by the Sixth Circuit, "[t]he issue in this case is whether defendants could have complied with their alleged duty under New York law to have designed a safer drug before submitting [the

[6] *See supra* n.1.

medication] for approval to the FDA or to change its formulation post-approval, while simultaneously complying with federal law." *Id.* at 294. After careful analysis, the Sixth Circuit answered both questions in the negative.

First, the Sixth Circuit held that the plaintiff's "post-approval design defect claim is clearly preempted by federal law" because the plaintiff's suggested design change, reducing the dosage of estrogen, amounted to a "major change" in the medication in violation of 21 C.F.R. § 314.70(b)(2)(i). *Id.* at 298. The court listed several "minor changes" that would not require prior approval from FDA, such as "[t]he deletion or reduction of an ingredient intended to affect only the color of the drug product" and "[a] change in the size and/or shape of a container containing the same number of dosage units," before concluding "to the extent [plaintiff] argues that defendants should have altered the formulation of [the medication] after the FDA had approved [it], we find this claim clearly preempted." *Id.* (citing 21 C.F.R. § 314.70(d)(2)(ii), (iv)).

Second, the Sixth Circuit held that even if "there is no federal law that would have prohibited defendants from designing a different drug in the first instance," defendants had no such duty and plaintiff's argument to the contrary was speculative and "too attenuated." *Id.* at 299.

> To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed [the medication] differently, the FDA would have approved the alternate design. Next, we would have to assume that [plaintiff] would have selected this method of birth control. Further yet, we would have to suppose that this alternative design would not have caused [plaintiff] to suffer a stroke. This is several steps too far.

*Id.*

Here, too, Plaintiffs' design defect claims are preempted by federal law. Under the FDCA, any change to an approved drug application must be approved by FDA before it is implemented, and any unapproved change renders the drug a new, unapproved drug under the FDCA. *See* 21 U.S.C. § 355(a). Thus, a design change to the formulation of Lexapro—which itself would

constitute a new and different drug—would require FDA approval. It is therefore impossible for Lexapro to be unilaterally redesigned without violating federal law.

Plaintiffs cannot avoid preemption by arguing that Lexapro should have been formulated differently at the outset (*i.e.*, prior to FDA approval). Under Sixth Circuit precedent, Defendant had no duty prior to FDA approval to design a different drug. *Yates,* 808 F.3d at 299–300. "To imagine such a pre-approval duty exists," this Court "would have to speculate" that: (i) FDA would have approved the alternative design; (ii) that Plaintiffs would have been prescribed and used the alternative design during pregnancy; and (iii) that their children would not have had the alleged injury as a result of Plaintiffs' ingestion of the alternative design. *Id.* at 299. Such argument is "too attenuated" to stand, as a matter of law. *Id.*

Many other decisions in this District are in accord. In *Rheinfrank v. Abbott Laboratories, Inc.*, 137 F. Supp. 3d 1035 (S.D. Ohio 2015), *aff'd*, 680 F. App'x 369 (6th Cir. 2017), plaintiff alleged that her child had injuries from her use of an antiepileptic drug during pregnancy. The court concluded the plaintiff's argument that the defendants could sell a different drug or "tweak the [drug's] molecule to make it safer" was preempted, since "[c]reating an alternative design would require changing the composition of an FDA-approved drug, which is prohibited by federal law." *Id.* at 1040–41.

The court in *Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 872–75 (N.D. Ohio 2014), reached the same conclusion, holding the plaintiff's design defect claim regarding a birth control patch was preempted because "it was impossible for the Defendants to comply with both its state-law duty to alter the composition of the drug, and its federal-law duty not to alter an FDA-approved design." *See also Fleming v. Janssen Pharms., Inc.,* 186 F. Supp. 3d 826, 833–34 (W.D. Tenn. 2016).

Even courts not bound by *Yates* cite it favorably and find it persuasive in holding design defect claims preempted. *See Evans v. Gilead Scis., Inc.,* 2020 WL 5189995, at *10 (D. Haw. 2020); *Javens v. GE Healthcare Inc.*, 2020 WL 2783581, at *6 (D. Del. 2020), *report and recommendation adopted*, 2020 WL 7051642 (D. Del. 2020); *Smith v. GE Healthcare Inc.,* 2020 WL 1880787, at *5 (W.D. La. 2020), *report and recommendation adopted,* 2020 WL 1875644 (W.D. La. 2020); *Gustavsen v. Alcon Labs., Inc.*, 272 F. Supp. 3d 241, 254–56 (D. Mass. 2017).

Accordingly, Plaintiffs' design defect claims are preempted by federal law and should be dismissed.

**B. Plaintiffs' Common Law Claims Fail Under State Law.**

Plaintiffs allege common law claims for strict liability, negligence, breach of implied and express warranty, and failure to warn, but do not specify which state's law they seek to apply to which Plaintiff's claims. Plaintiffs do, however, allege where they live.[7] To the extent they reside in the same state where they allegedly sustained their injuries, that locale presumptively governs the choice of law analysis.[8] *See Morgan v. Biro Mfg. Co.*, 474 N.E.2d 286, 289 (Ohio 1984).

Two of the three states at issue, Ohio and New Jersey, have product liability acts that subsume common law claims relating to products. Consequently, Plaintiffs Bossetti's and DiMeglio's state law claims are legally invalid. The third state, Virginia, does not permit recovery on a strict liability theory in product liability cases. Thus, Plaintiff Guida's strict liability claims fail as a matter of law.

[7] Plaintiff Bossetti is a citizen and resident of Ohio, Compl. ¶ 1; Plaintiff DiMeglio is a citizen and resident of New Jersey, *id.* ¶ 2; and Plaintiff Guida is a citizen and resident of Virginia, *id.* ¶ 3.
[8] For purposes of this motion, Defendant assumes, without conceding, that each Plaintiff's home state is the state where the alleged injury occurred. Defendant reserves all rights regarding choice of law.

**1. Ohio's PLA precludes Plaintiff Bossetti's common law claims.**

Plaintiff Bossetti's claims under Ohio law all fail because they are abrogated by the express terms of the Ohio Product Liability Act (OPLA). Under Ohio law, product liability claims include all causes of action that seek to recover damages for injury caused by an alleged defect in a product, and the OPLA governs all such claims. *See* Ohio Rev. Code § 2307.71(A)(13); *accord Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 917–22 (N.D. Ohio 2009). The current version of the OPLA, effective as of 2005, states that it is "intended to abrogate all common law product liability claims or causes of action." *Id.* § 2307.71(B).

Since the 2005 amendment to the OPLA, courts routinely dismiss non-statutory product liability claims brought under Ohio common law. For example, in *Krumpelbeck v. Breg, Inc*., 491 F. App'x 713, 721 (6th Cir. 2012), the Sixth Circuit affirmed the district court's dismissal of an Ohio plaintiff's common law claims of breach of express warranty, breach of implied warranty, and negligent misrepresentation and fraud "[b]ecause they were abrogated by the 2005 amendment to the OPLA." The court in *McManus v. Smith & Nephew, Inc*., 2020 WL 127702, at *3 (S.D. Ohio 2020), similarly dismissed plaintiff's non-statutory claims for negligence and breach of express and implied warranty, among others, because they "are all abrogated by the OPLA."

Here, Plaintiff Bossetti attempts to assert non-statutory, common law claims for strict liability, negligence, breach of implied and express warranty, and failure to warn. All such claims are abrogated by the OPLA. This Court should therefore dismiss those claims as a matter of law.

**2. New Jersey's PLA precludes Plaintiff DiMeglio's common law claims.**

Plaintiff DiMeglio's common law claims for strict liability, negligence, breach of implied warranty, and failure to warn all fail because they are subsumed by the New Jersey Product Liability Act (NJPLA). The NJPLA provides the "exclusive remedy" for alleged "harm caused by a product." *Bailey v. Wyeth, Inc.*, 37 A.3d 549, 580 (N.J. Super. Ct. Law. Div. 2008), *aff'd sub*

*nom. DeBoard v. Wyeth, Inc.*, 28 A.3d 1245 (N.J. Super. Ct. App. Div. 2011). The NJPLA defines a product liability action as "any claim or action brought by a claimant for harm" caused by a product, irrespective of the theory underlying the claim, except action for harm caused by breach of an express warranty. N.J. Stat. Ann. § 2A:58C-1(b)(3). The NJPLA's statutory definition is "both expansive and inclusive, encompassing virtually all possible causes of action in relating to harms caused by consumer and other products." *Sinclair v. Merck & Co.*, 948 A.2d 587, 595 (N.J. 2008) (citation omitted).

In *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 596–97 (D.N.J. 2015), the court observed that "New Jersey law no longer recognizes breach of implied warranty, negligence, and strict liability as viable separate claims for harm deriving from a defective product." As such, and in accord with other courts applying New Jersey law that "have consistently dismissed product liability claims based on those common-law theories," it dismissed those counts as a matter of law. *Id.* at 597 & n.5 (collecting cases). Because the NJPLA precludes Plaintiff DiMeglio's New Jersey law claims for strict liability, negligence, breach of implied warranty, and failure to warn, those counts should be dismissed as a matter of law.

**3. Virginia law precludes Plaintiff Guida's strict liability claim.**

Plaintiff Guida's strict liability claim fails under Virginia law because "Virginia has not adopted a strict liability regime for products liability." *Evans v. NACCO Materials Handling Grp., Inc.*, 810 S.E.2d 462, 469 (Va. 2018). Under Virginia law, a plaintiff can only bring a product liability claim under either a negligence theory or an implied warranty theory. *Id.* In *Henderson v. Boston Scientific Corp.*, for example, the court held plaintiff's "strict liability claims fail as a matter of law" because "Virginia law does not 'permit tort recovery on a strict liability theory in products liability cases.'" 2021 WL 3465074, at *3 (E.D. Va. 2021) (quoting *Sensenbrenner v.*

*Rust, Orling & Neale, Architects, Inc.*, 374 S.E.2d 55, 57 n.4 (Va. 1988)). Thus, Plaintiff Guida's strict liability claim should be dismissed as a matter of law.

### C. Plaintiffs' Punitive Damages Demands Are Barred by Ohio and New Jersey Law.

Plaintiffs seek an award of punitive damages, Compl. ¶ 158(d), but under Ohio and New Jersey law and federal preemption principles, Plaintiffs Bossetti and DiMeglio cannot recover punitive damages in a case involving an FDA-approved medicine. The Court should thus dismiss those Plaintiffs' punitive damages demands, as a matter of law.

Under the OPLA, punitive damages are unavailable when a drug "was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the 'Federal Food, Drug, and Cosmetic Act.'" Ohio Rev. Code § 2307.80(C)(1). An exception exists if the plaintiff can show that the manufacturer fraudulently withheld from or misrepresented to FDA information material and relevant to the plaintiff's harm. *Id.* § 2307.80(C)(2). Similarly, the NJPLA explicitly precludes punitive damages claims involving a medication that was "subject to premarket approval or licensure by the federal Food and Drug Administration … and was approved or licensed; or is generally recognized as safe and effective." N.J. Stat. Ann. § 2A:58C–5(c); *accord Lyles v. McNeil-PPC, Inc.*, 2014 WL 12480482, at *4 (N.J. Super. Ct. Law Div. 2014). Like Ohio, New Jersey's PLA includes a narrow exception to this general rule of immunity from punitive damages under the so-called "fraud-on-the-FDA" exception. *Id*.

Under Ohio and New Jersey law, because FDA approved Lexapro as a safe and effective medicine in 2002, Plaintiff cannot recover punitive damages unless the fraud-on-the-FDA exception applies. *See* Ohio Rev. Code § 2307.80(C)(1)-(2); N.J. Stat. Ann. § 2A:58C–5(c). But Plaintiffs do not and cannot allege that FDA ever made a determination of fraud regarding Lexapro.

Indeed, the FDA is only mentioned ***once*** in Plaintiffs' Complaint in reference to a different drug. *See* Compl. ¶ 16. Nowhere in their Complaint do Plaintiffs allege that Defendant knowingly withheld or misrepresented required information to FDA, or that such information (if it existed) was material and relevant to the harm in question. This omission warrants dismissal of Plaintiffs' punitive damages demands as a matter of law.

Even if the Complaint sufficiently alleged fraud on the FDA (and it does not), Plaintiffs Bossetti's and DiMeglio's punitive damages claim is preempted by federal law. Under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350–53 (2001), the FDCA impliedly preempts a claim that a manufacturer committed fraud on the FDA.

In *Garcia v. Wyeth-Ayerst Laboratories*, the Sixth Circuit applied *Buckman* to a Michigan statute with an analogous framework to the OPLA's punitive damages provision and held the fraud-on-the-FDA exception was preempted and unavailable unless "the FDA *itself* determines that a fraud has been committed on the agency during the regulatory-approval process." 385 F.3d 961, 966 (6th Cir. 2004). Thus, "a punitive-damages claim for an FDA-approved drug is allowed under Ohio law *only if* the FDA has made a finding of either fraud or misrepresentation." *Monroe v. Novartis Pharms. Corp.*, 29 F. Supp. 3d 1115, 1130 (S.D. Ohio 2014); *accord In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, 2013 WL 587655, at *14 (N.D. Ohio 2013). The Complaint here is devoid of such allegations. A punitive damages claim is thus not legally cognizable under Ohio law.

As for New Jersey, in *McDarby v. Merck & Co.*, 949 A.2d 223, 271–76 (N.J. Super. Ct. App. Div. 2008), the New Jersey Appellate Division reversed a punitive damages award against a drug manufacturer, holding that claims for punitive damages under the NJPLA were preempted by federal law under *Buckman*. Following *McDarby*, courts have consistently held that the fraud-on-

the-FDA exception in N.J.S.A. § 2A:58C–5(c) is impliedly preempted and forecloses punitive damages claims in product liability cases involving FDA-approved medications. *See Nelson v. Biogen Idec Inc.*, 2013 WL 1700918, at *2–3 (D.N.J. 2013); *Taylor v. McNeil-PPC, Inc.*, 2015 WL 12681605, at * 11 (N.J. Super. Ct. Law Div. 2015); *Mathews v. Novartis Pharms. Corp.*, 953 F. Supp. 2d 811, 816 (S.D. Ohio 2013) (applying New Jersey law); *Zimmerman v. Novartis Pharms. Corp.,* 889 F. Supp. 2d 757, 777–78 (D. Md. 2012) (same). This Court should do the same here.[9]

## V. CONCLUSION

For all the foregoing reasons, the Court should grant Defendant's motion to dismiss.

Dated: January 9, 2023

Respectfully submitted,

*/s/ Jennifer Snyder Heis*

Jennifer Snyder Heis (0076181)
John R. Ipsaro (0062300)
ULMER & BERNE LLP
312 Walnut Street, Suite 1400
Cincinnati, Ohio 45202
Telephone: 513-698-5058
Facsimile: 513-698-5059
jheis@ulmer.com
jipsaro@ulmer.com

[9] Any attempt by Plaintiffs to avoid preemption by characterizing their claims as not based on fraud on the FDA would be misguided. "Regardless of how the plaintiff styles a state claim, if it is a claim that could not be articulated but for the existence of a federal requirement that was allegedly violated, it is functionally equivalent to a claim that is grounded solely on the federal violation, and is therefore impliedly preempted." *Cornett v. Johnson & Johnson*, 998 A.2d 543, 560 (N.J. Super. Ct. App. Div. 2010), *aff'd in relevant part and modified*, 48 A.3d 1041 (N.J. 2012).

Bert L. Wolff
(*motion for admission PHV to be filed*)
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, New York 10036-6797
Telephone: 212-698-3548
Facsimile: 212-698-3599
bert.wolff@dechert.com

Jonathan S. Tam
(*motion for admission PHV to be filed*)
DECHERT LLP
One Bush Street
San Francisco, CA 94104-4446
Telephone: 415-262-4518
Facsimile: 415-262-4555
jonathan.tam@dechert.com

***Attorneys for Defendant***
***Allergan Sales, LLC***

**CERTIFICATE OF SERVICE**

I hereby certify that a true and accurate copy of the foregoing was electronically filed on January 9, 2023. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system and copies will be mailed to those parties who are not served via the Court's system.

/s/ *Jennifer Snyder Heis*
Jennifer Snyder Heis (0076181)